K082466

5. 510(k) Summary as required by 21 CFR 807.92(c)

510(k) Owner:
Vertebration, Inc.
3375 Brentwood Court
Powell, OH 43065
Phone: (614) 437-2027
Facsimile: (614) 437-2034

JAN - 9 2009

Contact person:
Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
310 Terrace Avenue
Suite 201
Cincinnati, OH 45220
Phone: (513) 961-8200
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Date: August 22, 2008

Trade Name: XYcor™ Spinal Implant for Minimally Invasive Spinal Surgery

Common name: Vertebral body replacement device

Classification Name: Spinal Intervertebral body fixation orthosis
21 CFR 888.3060,

Product Code: MQP

Identification of a Legally Marketed Predicate Device
As a Vertebral Body Replacement Device, the XYcor™ Spinal Implant V2-25 small size is substantially equivalent to the XYcor™ standard and large sizes marketed by Vertebration, 510(k) Premarket Notification Number: K070082, FDA Product Code MQP.

General Description
The XYcor™ Spinal Implant is a spinal implant fabricated from titanium that can be used as a vertebral body replacement device or an intervertebral body fusion device. The XYcor™ Spinal Implant deploys with a self-locking mechanism. The footprint of XYcor™ Spinal Implant V2-25 before and after deployment is of comparable size and shape to the other sizes of the XYcor™ implant.

Intended Use

The XYcor™ Spinal Implant is indicated for use as a vertebral body replacement device intended for use in the thoracic and/or thoracolumbar spine (T3-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The XYcor™ Spinal Implant is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The XYcor™ Spinal Implant is intended for use with bone graft and supplemental internal fixation for vertebral body replacement. The supplemental internal fixation systems that may be used with the XYcor™ System include Medtronic Sofamor Danek TSRH 3D, DePuy Spine Expedium or Monarch pedicle screw fixation systems, Biomet, Polaris, Array or Omega-21 pedicle screw fixation systems, and other pedicle screw-rod/plate fixation systems that have biomechanical properties similar to those of the above-listed systems, including trans-facet fixation systems but excluding semi-rigid or flexible rod-screw systems.

The XYcor™ Spinal Implant is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e., facet screw fixation systems, facet compression devices, and posterior pedicle screw and rod systems).

Performance Data

Mechanical testing was performed on the XYcor™ Spinal Implant V2-25 and the results are presented. The XYcor™ Spinal Implant V2-25 demonstrated sufficient strength for static and dynamic compressive and torsional loading modes and resistance to subsidence and expulsion. Mechanical testing performed on the XYcor™ Spinal Implant supports its use as a vertebral body replacement device.. The results did not raise any issues on the safety or effectiveness of the device.

Basis of Substantial Equivalence

The XYcor™ Spinal ImplantV2-25 is substantially equivalent to the other sizes of the XYcor™ Spinal Implant manufactured by Vertebration under 510(k) Premarket Notification Number K070082, FDA Product Code MQP, and regulation 21CFR§888.3060 (spinal intervertebral body fixation orthosis) in material, intended use, basic design concept, size of the footprint, and biomechanical properties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vertebration, Inc.
% Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
310 Terrace Avenue, Suite 201
Cincinnati, OH 45220

JAN - 9 2009

Re: K082466
Trade/Device Name: XYcor Spinal Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: January 2, 2009
Received: January 5, 2009

Dear Dr. Fant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K082466

Device Name: **XYcor™ Spinal Implant**

Indications for Use:

The XYcor™ Spinal Implant is indicated for use as a vertebral body replacement device intended for use in the thoracic and/or thoracolumbar spine (T3-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The XYcor™ Spinal implant is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X_____ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082466